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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/616,622

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Daniel M. Lafontaine

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

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05/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/616,622	Applicant(s) LAFONTAINE, DANIEL M.	
	Examiner DIANE YABUT	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16-29 and 31-41 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13, 16-29 and 31-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 02/21/2008.

The examiner acknowledges the amendments made to the claims.

Claims 1-14, 16-29, and 31-41 are pending in the application. Claims 11-12 and 14 are withdrawn from consideration.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-10, 13, 24-29, and 31-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lafontaine et al.** (U.S. Patent No. **5,964,782**) in view of **Linden et al.** (U.S. Patent No. **6,270,515**).

Claims 1, 16-20, 26, 33, and 34: Lafontaine et al. discloses a closure device comprising an elongate delivery member **334** having a distal end and a proximal end and a closure component **344** removably connected to the distal end of the delivery member, the closure component including a collapsible backing, movable between a non-collapsed position and a collapsed position, and a plurality of fibrous tissue engaging members disposed on the backing and oriented in a non-engaging orientation when traveling in a distal direction and in an engaging orientation when traveling in a proximal direction, the fibrous tissue engaging members entangling the backing when

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the backing is in the collapsed position (Figure 34A and col. 17, lines 39-51).

Lafontaine et al. also discloses a method of closing an opening **332** in a body comprising inserting distally through the opening a closure component **344** having collapsible pile backing with pile engaging hooks and tissue engaging hooks disposed thereon, withdrawing the closure component **344** proximally relative to the opening such that the tissue engaging hooks engage tissue adjacent the opening, and collapsing the collapsible pile backing so the pile engaging hooks engage portions of the pile backing (col. 17, lines 22-50). Lafontaine discloses the claimed device *except* for the backing having a generally conical shape with a center portion of the backing distally spaced from a periphery of the backing, and the backing center portion being collapsed proximally toward the backing periphery to have a generally disc shape, and manipulating a collapse actuator releasably coupled to the collapsible pile backing or closure component and operable to move the distal end of the collapsible backing under to a more proximal position under proximally directed force from the non-collapsed position to the collapsed position, and disconnecting the collapse actuator from the collapsible pile backing.

Linden et al. teaches manipulating a collapse actuator **524** releasably or detachably coupled to a collapsible backing **512** at its distal end and is received with a distal aperture in the closure component and extends distal to the distal aperture when the closure component is the non-collapsed position and the collapse actuator being operable to move the collapsible backing or closure component and operable to move the distal end of the collapsible backing under to a more proximal position under

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proximally directed force from a non-collapsed position or generally conical shape to a collapsed position or disc-shape and disconnecting the collapse actuator from the collapsible pile backing by passing proximally through the distal aperture and the collapsed closure component (Figures 17-20, col. 11, lines 13-16). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a collapse actuator releasably coupled to a collapsible backing, as taught by Linden et al., to Lafontaine et al. since it was known in the art that if a closure element is to remain in the tissue, an actuating mechanism must be effectively releasably coupled from the closure element to be effectively manipulated and subsequently detached after deployment and since it was also known in the art that closure devices with conical, elongate configurations more conveniently fit and maneuver through delivery sheaths and body lumens, and that collapsing to a disc shape offers more surface area coverage for closure of a body lumen.

Claims 2, 3, and 35: Lafontaine et al. discloses a backing formed in a generally elongate conformation, along a generally longitudinal axis of the backing, in the non-collapsed position, and the backing collapsed generally along the longitudinal axis when in the collapsed position (Figures 35 and 37B).

Claims 4, 5, 36 and 37: Lafontaine et al. discloses the fibrous tissue engaging members forming proximally facing hooks that are spaced along the backing from a proximal portion thereof to a distal portion thereof when the backing is in the non-collapsed position (Figure 35).

Claims 6 and 38: Lafontaine et al. discloses the hooks entangle in the backing located proximal of the hooks as the backing moves from the non-collapsed position to the collapsed position (col. 17, lines 38-43 and col. 18, lines 24-29).

Claims 7 and 39: Lafontaine et al. discloses the body cavity **332** is defined by generally smooth tissue and has fibrous tissue proximal thereof and wherein at least a subset of the plurality of hooks **4** are oriented to engage the fibrous tissue as the hooks travel in a proximal direction relative to the fibrous tissue (Figures 34A-34C and col. 17, lines 27-42).

Claims 8-10: Lafontaine et al. and discloses the claimed device, including a closure component having a first row of hooks disposed about a proximal end thereof including tissue piercing hooks that pierce tissue and pass along the generally smooth tissue without engaging the generally smooth tissue and engage the fibrous tissue as the closure component is moved proximally relative thereto (Figure 34A-34C and col. 19, lines 54-67), *except* for the closure component being generally conical.

Linden et al. teaches the closure component being generally conical (Figure 18) and it would have been obvious to one of ordinary skill in the art at the time of invention to provide a conical closure component, as taught by Linden et al., to Lafontaine et al. since it was known in the art that closure devices with conical, elongate configurations more conveniently fit and maneuver through delivery sheaths and body lumens

Claim 13: Lafontaine et al. discloses an active actuator **388** having a distal engaging end disconnectably connecting the closure component to the delivery member and a

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proximal end receiving an actuation input and actuating the distal engaging end to release the closure component in response to the actuation input (col. 20, lines 14-19).

Claims 24 and 25: Lafontaine et al. discloses the closure component is formed of a biocompatible, bioabsorbable material (col. 4, lines 62-67).

Claim 27: Lafontaine et al. discloses inserting the closure component **344** with an elongate delivery member **334**, the closure component **344** being disposed at a distal end of the delivery member **334** (col. 17, lines 31-38).

Claim 28: Lafontaine et al. discloses disconnecting the closure component **344** from the distal end of the delivery member **334** (col. 18, lines 30-35).

Claim 29: Lafontaine et al. discloses exerting proximally directed force on the delivery member **334** after collapsing the collapsible pile (col. 18, lines 2-12).

Claim 31: Lafontaine et al. discloses the tissue engaging hooks being comprised of tissue piercing hooks that pierce the tissue when the tissue is engaged (col. 17, lines 38-40).

Claim 32: Lafontaine et al. discloses the opening **332** is in a body cavity defined by media and having adventitia adjacent thereto and wherein withdrawing comprises withdrawing the tissue engaging hooks proximally past the media to engage the adventitia (Figures 34A-34C and col. 17, lines 27-42).

Claims 40-41: Lafontaine et al. discloses the fibrous tissue engaging members and the backing being disposed on a same surface of the closure component comprising an exterior surface of the closure component (Figure 34A).

3. Claims 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Lafontaine et al.** (U.S. Patent No. **5,964,782**) in view of **Linden et al.** (U.S. Patent No. **6,270,515**), as applied to claim 16 above, and further in view of **Redmond et al.** (U.S. Patent No. **6,334,865**).

Claims 17-21: Lafontaine et al. and Linden et al. discloses the claimed device, including a collapse actuator (Linden et al.), *except* for the collapse actuator having a deformable hook at the distal end of the elongate member, the deformable hook being located distal of the distal aperture when the closure component is in the non-collapsed position, the deformable hook moving a distal end of the closure component to a more proximal position to collapse the closure component under proximally directed force applied to the elongate member, and the deformable hook deforming to pass through the distal aperture in the closure component.

Redmond et al. teaches a deformable hook, or wire, **22** at the distal end of a collapse actuator **20** that is received within a distal aperture in the closure component **26** and grasps the closure component and moves a distal end of the closure component to a more proximal position to collapse the closure component under proximally directed force applied to the elongate member and wherein the deformable hook is located distal of the distal aperture in the closure component **22** when the closure component is in the non-collapsed form, the deformable hook **22** capable of deforming to pass through the

distal aperture in the closure component **22** after the closure component **22** has moved to the collapsed position under continued application of proximally directed force on the collapse actuator **20** (Figures 1-4, col. 26-37). It would have been obvious to one of ordinary skill in the art to modify the collapse actuator by providing a deformable hook at the distal end of the elongate member, as taught by Redmond et al., to Lafontaine et al. and Linden et al., since it was known in the art that a deformable hooks are flexible and useful in manipulating devices in blood vessels and conveniently have a low profile when moving through the distal ends of elongate members, or actuators.

Claims 22-23: Lafontaine et al. discloses the wire **334** comprising a frangible, mechanically releasable connection to the distal end of the closure component (col. 20, lines 14-19).

Response to Arguments

4. Applicant's arguments with respect to claims 1-10, 13, 16-29, and 31-41 have been considered but are moot in view of the new ground(s) of rejection.

5. However, the examiner still relies on the Lafontaine et al., Linden et al., and Redmond et al. references.

6. The applicant generally argues that the Redmond et al. device involves a temporary barrier which is withdrawn from a patient whereas the devices of Lafontaine et al. and Linden et al. are permanent barriers and the combination would render the Redmond device unsatisfactory for its intended purpose. However, the teaching of Redmond et al. suggests that it is beneficial to collapse an elongate barrier member to a

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disc shape during deployment to properly serve as a barrier in a puncture, and the fact that it is a temporary barrier does not teach away from its beneficial method of deployment, and therefore it is a relevant and proper combination with Lafontaine et al. and Linden et al.

7. The applicant also generally argues that Linden et al. does not teach a detachable distal end received within a distal aperture of the closure component and positioned distal to the distal aperture, and that the expandable balloon 524 cannot be equated to a collapse actuator. The examiner disagrees. Linden et al. teaches the closure element 512 prior to expansion (Figure 18) which then is actuated by expandable balloon 524 (Figure 19) to collapse in the longitudinal direction, and therefore may be considered a collapse actuator. The distal end of the actuator 524 is also is received within the distal aperture of the closure component and positioned distal to the distal aperture and is detachable to the closure component (Figure 20).

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/

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Examiner, Art Unit 3734

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731